

ANCILLARY STUDIES GUIDELINES

(Revised: 11/97)

An ancillary study involves collection of data from or about Health ABC participants using procedures or measurements that are not included in the core protocol. All proposals for ancillary studies are initially reviewed by the Emerging Sciences Committee and then approved by the Steering Committee.

A. Who may submit a proposal?

Investigators are encouraged to conduct ancillary studies with the stipulation that such studies be scientifically sound and have little or no adverse impacts on the main study. Investigators outside of Health ABC are welcome to propose ancillary studies. However, at least one paid Health ABC investigator must be involved with every ancillary study proposal.

B. Proposal format

An investigator who wishes to conduct an ancillary study submits a written proposal to the chair of the Emerging Sciences Committee. The proposal, generally 2-5 pages in length, should include the following elements:

- 1) research question with clearly stated hypothesis
- 2) background and rationale for the study
- 3) a detailed description of the methods and procedures to be employed
- 4) an estimate of the sample size required to test the primary hypothesis (including the assumptions underlying the estimate)
- 5) a detailed estimate of the impact of the study on the main study: cost (including administration and data analysis), staff and participant time, coordinating unit costs, radiation exposure, and/or quantity of any biological specimen(s) to be consumed per participant.

C. Approval process

The Committee will review each application, considering 1) its scientific merit, 2) quality of the design and methods, and 3) the potential impact (both positive and negative) on the main study. The Emerging Sciences Committee will pass its review on to the full Steering Committee for a decision about approval or disapproval. Either Committee may ask the investigator to revise and resubmit the proposal before voting.

All ancillary studies will be reviewed by the Steering Committee along with the recommendations of the Emerging Sciences Committee. Ancillary studies must be approved by a 2/3 majority of members who participate in the vote.

D. Priorities

Priority will be given to proposals that are scientifically important. In general, proposals that augment or complement the main scientific aims of Health ABC will be favored over those that take advantage of Health ABC for more tangential purposes.

E. IRB approval

All ancillary studies must eventually be approved by the appropriate institutional review boards before they are performed, but IRB approval is not required to submit a proposal to the Emerging Sciences or Steering committees.

F. Funding

Proposals for funding ancillary studies must be approved by the Steering Committee before they are submitted to the funding agencies. Proposals for funding must include coverage of all the costs detailed in section D.5.

G. Changes after approval

If substantial changes in the design of the protocol or in the potential impact of the protocol on the main study occur after Steering Committee approval, then the investigators must submit a revised protocol to the Emerging Science Committee for review. If the changes are substantial, the Emerging Sciences Committee may submit the proposal for approval by the Steering Committee.

The Steering Committee may, by majority vote, terminate an ancillary study if it judges that a study has become too burdensome or its scientific value has diminished.

H. Data analysis

All data collected in ancillary studies will be included in the Health ABC database. The main Health ABC Investigator named in the proposal will arrange for analysis of the data by one of the Health ABC study units. The lead investigator(s) of the ancillary study will have first priority for first authorship on three analysis plans and papers that use data generated from the ancillary study. They will also retain the option of serving as co-authors of all other publications using that data in accord with the Health ABC publication guidelines.